Notice of Allowability	Application No.	Applicant(s)	
	10/823,932	NIELSEN ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the interviews of June 1 & 15, and July 5 & 6, 2006*.

2. ☒ The allowed claim(s) is/are *1-19*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☒ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date 20040513, 20040614
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☒ Other *IDS of 20050211*.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interviews with Nathan S. Cassell on 05 and 06 July 2006.

The application has been amended as follows:

Claims 1 and 3-11 have been replaced with the following:

1. (Currently Amended) A method of treating mammalian cancer cells deficient in functional p53, said method comprising contacting ~~cells from~~ said cancer cells with ~~a p53 tumor suppressor protein or with~~ a recombinant adenoviral vector comprising a nucleic acid encoding p53 tumor suppressor protein, which nucleic acid is expressed in said cells, and also contacting said cells with the polyprenyl-protein transferase inhibitor FPT39, such that one or more disease characteristics of the cells are **[[is]]** ameliorated, wherein the mammalian cancer cells are human breast, colorectal, pancreatic, or prostate cancer cells.

3. (Currently Amended) The method of claim 1, wherein said recombinant adenoviral vector comprises the adenovirus type 2 major late promoter or the human CMV promoter, the adenovirus type 2 tripartite leader cDNA and a human p53 cDNA, which are operably linked.

4. (Currently Amended) The method of claim 1, wherein said cells are first contacted with said ~~p53 tumor suppressor protein or with a~~ recombinant adenoviral vector comprising a nucleic acid encoding p53 and are subsequently contacted with said FPT39.

5. (Currently Amended) The method of claim 1, wherein said cells are first contacted with said FPT39 and subsequently contacted with said ~~p53 tumor suppressor protein or with a~~ recombinant adenoviral vector comprising a nucleic acid encoding p53.

6. (Currently Amended) The method of claim 1, wherein said cells are simultaneously contacted with said FPT39 and with said ~~p53 tumor suppressor protein or with a~~ recombinant adenoviral vector comprising a nucleic acid encoding p53.

7. (Currently Amended) The method of claim 1, wherein ~~said p53 tumor suppressor protein or~~ said recombinant adenoviral vector comprising a nucleic acid encoding p53 is dispersed in a pharmacologically acceptable excipient.

8. (Currently Amended) The method of claim 1, wherein ~~said p53 tumor suppressor protein or~~ said recombinant adenoviral vector comprising a nucleic acid encoding p53 and said FPT39 are dispersed in a single composition.

9. (Currently Amended) The method of claim 1, wherein said contacting cells with a ~~p53 tumor suppressor protein or said~~ recombinant adenoviral vector comprising a nucleic acid encoding p53 comprises contacting said cells with ~~said p53 tumor suppressor protein or~~ said recombinant adenoviral vector comprising a nucleic acid encoding p53 in a multiplicity of treatments each separated by at least about 6 hours.

10. (Currently Amended) A method of treating human breast, colorectal, pancreatic, or prostate cancer cells in a mammal, the method comprising administering to the mammal ~~a p53 tumor suppressor protein or~~ an adenoviral vector comprising a nucleic acid ~~sequence~~ encoding a p53 tumor suppressor protein, which nucleic acid is expressed in the cells, and also administering to the mammal the polyprenyl-protein transferase inhibitor FPT39, such that one or more disease characteristics of the cancer cells are **[[is]]** ameliorated.

11. (Currently Amended) A method of treating human breast, colorectal, pancreatic, or prostate cancer cells *in vitro*, the method comprising contacting ~~cells from~~ the cancer cells with ~~a 53 tumor suppressor protein or~~ an adenoviral vector comprising a nucleic acid ~~sequence~~ encoding a p53 tumor suppressor protein, which nucleic acid is expressed in the cells, and also contacting the cells with the polyprenyl-protein transferase inhibitor FPT39, such that one or more disease characteristics of the cancer cells are **[[is]]** ameliorated.

New claims 12-19 have been added.

12. (New) The method according to claim 10, wherein the cancer cells comprise human breast cancer cells.

13. (New) The method according to claim 10, wherein the cancer cells comprise human colorectal cancer cells.

14. (New) The method according to claim 10, wherein the cancer cells comprise human pancreatic cancer cells.

15. (New) The method according to claim 10, wherein the cancer cells comprise human prostate cancer cells.

16. (New) The method according to claim 11, wherein the cancer cells comprise human breast cancer cells.

17. (New) The method according to claim 11, wherein the cancer cells comprise human colorectal cancer cells.

18. (New) The method according to claim 11, wherein the cancer cells comprise human pancreatic cancer cells.

19. (New) The method according to claim 11, wherein the cancer cells comprise human prostate cancer cells.

The following is an examiner's statement of reasons for allowance:

Restriction to one of the following inventions was required under 35 U.S.C. 121:

I. Claims 1-11, drawn to treatment of cancer cells with p53 protein, classified in class 514, subclass 2.

II. Claim1-11, drawn to treatment of cancer cells with and adenoviral vector expressing p53 protein, classified in class 424, subclass 93.2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are directed to related methods. The related inventions are distinct if the inventions as claimed do not overlap in scope, i.e., are mutually exclusive; the inventions as claimed are not obvious variants; and the inventions as claimed are either not capable of use together or can have a materially different design, mode of operation, function, or effect. See MPEP § 806.05(j). In the instant case, the inventions do not overlap in scope. There is no evidence that that they are obvious over each other. They are not disclosed as being used together. They have materially different design and mode of operation.

Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art in view of their different classification and the inventions require a different field of search (see MPEP § 808.02), restriction for examination purposes as indicated is proper.

During a telephone conversation with Nathan Cassell on 01 June 2006 a provisional election was made with traverse to prosecute the invention of Group II, claims 1-11. As indicated below, Applicant later authorized amendment of the claims to delete the non-elected subject matter of Group I, thus rendering the restriction requirement moot.

This application is a continuation of allowed application 09/311,772, which was abandoned before issue. The instant claims are directed to subject matter that had been allowed in the '772 application as being non-obvious over either Doll et al., WO 97/23478, or Sebti et al., WO 96/21456; and Fujiwara et al., Cancer Res. 54: 2287-2291, 1994, and Gregory et al., WO 95/11984, due to unexpected synergy between expression of p53 from the adenoviral vector and treatment with FPT39 in treatment of the recited types of cancer cells. The new claims were added at the request of Applicant.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Scott D. Priebe

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Art Unit 1633